Estimated Total Annual Burden Hours: 2,352.

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–10987 Filed 5–6–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–E–0397]

Determination of Regulatory Review Period for Purposes of Patent Extension; ISTENT TRABECULAR MICRO-BYPASS STENT

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for the ISTENT TRABECULAR MICRO-BYPASS STENT and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written petitions (two copies are required) and written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit petitions electronically to *http://www.regulations.gov* at Docket No. FDA–2013–S–0610.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Management, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Campus, Rm. 3180, Silver Spring, MD 20993, 301–796–7900.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For medical devices, the testing phase begins with a clinical investigation of the device and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the device and continues until permission to market the device is granted. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a medical device will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(3)(B).

FDA has approved for marketing the medical device ISTENT TRABECULAR MICRO-BYPASS STENT. ISTENT TRABECULAR MICRO-BYPASS STENT is indicated for use in conjunction with cataract surgery for the reduction of intraocular pressure in adult patients with mild to moderate open-angle glaucoma currently treated with ocular hypotensive medication. Subsequent to this approval, the USPTO received a patent term restoration application for the ISTENT TRABECULAR MICRO-BYPASS STENT (U.S. Patent No. 6,626,858) from Glaukos Corporation, and the USPTO requested FDA's assistance in determining this patent's eligibility for patent term restoration. In a letter dated January 30, 2014, FDA advised the USPTO that this medical device had undergone a regulatory review period and that the approval of the ISTENT TRABECULAR MICRO-BYPASS STENT represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for the ISTENT TRABECULAR MICRO-BYPASS STENT is 2,820 days. Of this time, 1,535 days occurred during the testing phase of the regulatory review period, while 1,285 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 520(g) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360j(g)) involving this device became effective:* October 7, 2004. FDA has verified the applicant's claim that the date the investigational device exemption (IDE) required under section 520(g) of the FD&C Act for human tests to begin became effective October 7, 2004.

2. *The date an application was initially submitted with respect to the device under section 515 of the FD&C Act (21 U.S.C. 360e):* December 19, 2008. FDA has verified the applicant's claim that the premarket approval application (PMA) for the ISTENT TRABECULAR MICRO-BYPASS STENT (PMA P080030) was initially submitted December 19, 2008.

3. *The date the application was approved:* June 25, 2012. FDA has verified the applicant's claim that PMA P080030 was approved on June 25, 2012.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 5 years of patent term extension.

Anyone with knowledge that any of the dates as published are incorrect may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments and ask for a redetermination by July 6, 2015. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by November 3, 2015. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments and written or electronic petitions. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. If you submit a written petition, two copies are required. A petition submitted electronically must be submitted to *http://www.regulations.gov,* Docket No. FDA–2013–S–0610. Comments and petitions that have not been made publicly available on *http://www.regulations.gov* may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–10999 Filed 5–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–0138]

Questions and Answers Regarding Mandatory Food Recalls; Draft Guidance for Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for industry on the implementation of the mandatory food recall provisions of the FDA Food Safety Modernization Act (FSMA). The guidance is in the form of Questions and Answers and provides answers to common questions that might arise about the mandatory recall provisions and FDA's plans for their implementation.

DATES: Although you may comment on any guidance at any time, to ensure that the Agency considers your comments on this draft guidance before it completes a final version of the guidance, submit electronic or written comments on the draft guidance by July 6, 2015.

ADDRESSES: Submit written requests for single copies of the guidance to the Outreach and Information Center (HFS–009), Center for Food Safety and Applied Nutrition (HFS–317), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Cecilia M. Wolyniak, Food and Drug Administration, WO32 Rm. 4352 HFC–210, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–8209.

SUPPLEMENTARY INFORMATION:

I. Background

FDA's mandatory food recall authority went into effect when FSMA was enacted on January 4, 2011. Section 423 of the Federal Food, Drug and Cosmetic Act (FD&C Act), as added by section 206 of FSMA, gives FDA the authority to order a responsible party to recall an article of food where FDA determines that there is a reasonable probability that the article of food (other than infant formula) is adulterated under section 402 of the FD&C Act [21 U.S.C. 342] or misbranded under section 403(w) of the FD&C Act [21 U.S.C. 343(w)] and that the use of or exposure to such article will cause serious adverse health consequences or death to humans or animals (SAHCODHA).

FDA is announcing the availability of a draft guidance for industry entitled ''Questions and Answers Regarding Mandatory Food Recalls; Draft Guidance for Industry.'' The draft guidance provides answers to common questions that might arise about the mandatory recall provisions and FDA's plans for their implementation.

This guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent our current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance does not refer to any information collection provisions found in FDA regulations. Collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We conclude that the Draft Guidance for Industry: Questions and Answers Regarding Mandatory Food Recalls is not subject to Paperwork Reduction Act of 1995.

III. Comments

Interested persons may submit either written comments regarding the guidance to the Division of Dockets Management (see **ADDRESSES**) or electronic comments regarding the guidance to *http://www.regulations.gov.* It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

IV. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: May 1, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–11009 Filed 5–6–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2029]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Administrative Practices and Procedures; Formal Evidentiary Public Hearing

AGENCY: Food and Drug Administration, HHS.